

Applicant : Nai-Kong CHEUNG  
U.S. Serial No.: 10/621,027  
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REMARKS

By this Amendment, Applicant has canceled claims 67-119 without prejudice to the Applicant's right to pursue these matters in a future application. Applicant has added new claims 120-148. Support for new claims can be found inter alia in the canceled claims 67-119.

Further, support for "synergistic effect" can be found inter alia on page 7, lines 5-21 of the specification.

Further, support for "oral route" can be found inter alia on page 26, lines 5-18

Accordingly, there is no issue of new matters, and Applicant respectfully requests the entry of this Amendment. Upon entry, claims 120-148 are pending under examination.

1. Rejection Under 35 U.S.C. Section 102(B)

Examiner's rejection of claims 67, 80, 82-85 under 35 U.S.C. section 102(b) by Jamas et al. has been maintained.

The Examiner states:

The statement... "capable of enhancing efficacy of an antibody" and "foreign to the immune system of the host" is given no patentable weight... The statement of intended use of the glucan, i.e., enhancing efficacy of an antibody, is given no patentable weight and is not a component of the composition. [T]he only component of the composition is the glucan, which comprises a 1,3 beta backbone with mixed linkages. However, the phrase, "with mixed linkages," can be reasonable interpreted to refer to either linkages in the backbone itself, or

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linkages that branch off from the backbone. Therefore, the glucan taught by Jamas et al. satisfies this limitation. See page 3, 1<sup>st</sup> para. of July 13, 2005 Final Office Action.

In response but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 67, 80 and 82-85 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

Applicant further maintains that Jamas et al. disclose a soluble glucan preparation, also referred to as PGG, (See col. 1 line 35 of Jamas et al.) for protecting an immunologically intact host against infection after surgery (See col. 8, lines 29-31 of Jamas et al.). However, a multicenter study using PGG was "terminated before anticipated completion because of an increased incidence of adverse effects in patients receiving PGG-glucan." See University Of Strathclyde/Cancer Research UK, Medicinal Mushrooms: Their therapeutic properties and current medical usage with special emphasis on cancer treatments, Chapter 8 (Smith, Rowan, Sullivan, May 2002), available at [http://www.fruiting-bodies.co.uk/cancer\\_research/cr\\_chapter8.htm](http://www.fruiting-bodies.co.uk/cancer_research/cr_chapter8.htm) (attached herein as **Exhibit A**). See also Dellinger et al., Effect of PGG-glucan on the Rate of Serious Postoperative Infection or Death Observed after High-Risk Gastrointestinal Operations, Arch Surg. Vol. 134, p. 977-983 (1999) (See Exhibit A of Applicants' March 31, 2005 Response)

In contrast, Applicant's invention is directed to a composition comprising a glucan, wherein the glucan is administered by oral route, in an amount wherein the glucan and an antibody administered to a subject have synergistic effect.

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Anticipation is found only when a prior art reference discloses, either expressly or inherently, each and every element of a claimed invention. See Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354, 1367 (Fed. Cir. 2004) (attached herein as **Exhibit B**). Here, Jamas et al. do not recite each and every element of Applicant's claimed composition. For example, Jamas et al. do not teach or suggest to one of ordinary skill in the art that an orally administered glucan composition and an antibody administered to a subject have synergistic effect, or that the efficacy of an antibody administered to a subject is synergistically enhanced by the oral administration of the glucan composition. Jamas et al. also do not teach or suggest what amount of glucan is required to produce the synergistic effect or how to determine such an amount.

In addition, while Applicant's claimed composition recite an amount wherein the glucan and an antibody administered to a subject have synergistic effect (See claim 120), Jamas et al. describes a composition "administered to an animal or a human in an amount sufficient to produce immune system enhancement." Therefore, Jamas et al. do not explicitly or inherently disclose Applicant's claimed invention.

Further, while Applicant does not intend to be bound by any theory, it is believed that normal T cells and B cells are not required for the synergistic effect. See page 29, lines 29-32, of the specification. Therefore, the synergy between the glucan composition of the claimed invention and an antibody would not be affected in an immuno-compromised subject with defective T- or B-cells, such as a cancer patient undergoing chemotherapy. In

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contrast, Jamas et al. states that "PGG appears to prime the mononuclear cells to release elevated levels of monokines (TNF, GM-CSF, M-CSF, IL-6) upon subsequent stimulation with endotoxin or other infectious agents." See col. 5, lines 42-46, of Jamas et al. Therefore, T or B cells are required. Since the mechanism of action of the claimed composition and the glucan preparation as described in Jamas et al. are different, the dosage response relationship and the amount for the claimed use should be different.

Accordingly, Jamas et al. cannot anticipate Applicant's claimed composition because Jamas et al. do not teach or suggest each and every element of Applicant's claimed composition. Therefore, Applicant respectfully requests the reconsideration and withdrawal of this ground of rejection.

**2. Rejection Under 35 U.S.C. Section 103(A)**

Examiner's rejection of claims 68-79 and 83 under 35 U.S.C. section 103(a) by Jamas et al., Dorothee Herlyn, Yan et al., Marcinaï, Cheever et al., Chu et al., and Lane et al. has been maintained.

The Examiner states:

The amendments to the claims inserting statements of intended use for the glucan are given no patentable weight. Additionally, the statement further defining the glucan to have mixed linkages can be reasonable interpreted to include branched glucan as taught by the prior art references cited on the record. See page 3, 2<sup>nd</sup> para. of July 13, 2005 Final Office Action.

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The Examiner rejected claims 81 and 83 under 35 U.S.C. section 103(a) by Jamas et al., Dorothee Herlyn, Yan et al., Marcinaï, Cheever et al., Chu et al., and Lane et al. has been maintained. The Examiner states that "... the language 'mixed linkages' can reasonably be interpreted to include 1,3 beta backbone glucans with branches, which is taught by the prior art of record. See page 5, 1<sup>st</sup> para. of July 13, 2005 Final Office Action.

In response, Applicant respectfully traverses the Examiner's above ground of rejection. The references cited by the Examiner do not teach or suggest, alone or in combination, a glucan composition which has synergistic effect when administered in an appropriate amount with an antibody to a subject. The appropriate amount of the composition of the claimed invention which can synergistically enhance the efficacy of the antibody can be readily determined by one of ordinary skill in the art based on the disclosure of this Application.

Accordingly, the cited references do not render Applicant's claimed composition obvious. Therefore, Applicant respectfully requests the reconsideration and withdrawal of this ground of rejection.

### 3. Withdrawal of claims 89-119

The Examiner states that:

Newly submitted claims 89-119 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented claims contain glucan and an antibody, wherein the antibody governs the classification of the invention, classified in class 436/547. See page 4, 1<sup>st</sup> para. of July 13, 2005 Final Office Action.

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In response but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 89-119 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

4. Rejection Under 35 U.S.C. Section 112, second paragraph

Claims 67, 81, and 88 are rejected under 35 U.S.C. § 112, second paragraph. The Examiner states that "[t]he limitation of 'mixed linkages' found in these claims is indefinite and ambiguous." See page 5, 2<sup>nd</sup> para. of July 13, 2005 Final Office Action. The Examiner also rejected claims 86 and 87 under 35 U.S.C. § 112, second paragraph. The Examiner states that "claims that depend from an indefinite claim are also indefinite if they fail to obviate the reason the claim(s) from which they depend are rejected." See page 5, 2<sup>nd</sup> para. of July 13, 2005 Final Office Action.

In response but without conceding the correctness of the Examiner's position and to expedite the prosecution of this Application, Applicant has canceled claims 67, 81, 86, 87 and 88 without prejudice. New claims do not contain the above-mentioned issues, thereby rendering this ground of rejection moot.

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CONCLUSION

Applicant respectfully maintains that the rejections raised by the Examiner in the July 13, 2005 Final Office Action have been fully addressed. Therefore, this Application is in full compliance with all requirements. Accordingly, Applicant respectfully urges the Examiner to reconsider and withdraw all rejections in the Non-final Office action and place this Application in conditions for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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